

MAY 12 2000

## Exhibit 8

Special 510(k)  
Summary

Company name: Carmel Pharma AB

## Product Name:

PhaSeal® - a system for closed handling of parenteral drugs.

## Device names:

Protector 21  
Protector 50  
Protector 14  
Injector Luer Lock  
Infusion Adapter

PhaSeal is a closed system for handling of parenteral drugs where the component devices are dedicated to each other to create the system. These single use devices are designed to promote safe handling of medications, particularly cytotoxic drugs. Leakage of drug into the environment is effectively avoided during all three phases of drug handling when the PhaSeal system is used: the preparation of the drug, the administration of the drug to the patient, and waste handling.

All drug transferring utilizes a patented double membrane technique. Each component device is sealed off with an elastomeric membrane. The membranes are joined together and transfer is made via a specially cut injection cannula. When the component devices of the system are separated after transfer, the membranes act as tight seals that prevent leakage.

**PhaSeal, Protector 21 - Drug Vial Transfer Adapter**

The **Protector 21** is fitted to the drug vial and is used as a docking station between the drug vial and Injector. In addition the **Protector 21** equilibrates the pressure difference which occurs when fluid or air is added or removed from the drug vial. Liquid transfer takes place through tightly fitting elastomeric membranes to minimize exposure to potentially hazardous drug aerosols and spills that occur during the reconstitution, administration and disposal processes. The "fingers" surrounding the neck of the drug vial has been improved for the fitting to the drug vial. The volume of the expansion chamber is 20 ml.

**PhaSeal, Protector 50 - Drug Vial Transfer Adapter**

The **Protector 50** is fitted to the drug vial and is used as a docking station between the drug vial and Injector. In addition the Protector equilibrates the pressure difference which occurs when fluid or air is added or removed from the drug vial. Liquid transfer takes place through tightly fitting elastomeric membranes to minimize exposure to potentially hazardous drug aerosols and spills that occur during the reconstitution, administration and disposal processes. The "fingers" surrounding the neck of the drug vial has been improved for the fitting to the drug vial. The volume of the expansion chamber is 50 ml.

**PhaSeal, Protector 14 - Drug Vial Transfer Adapter**

The **Protector 14** is fitted to the drug vial and is used as a docking station between the drug vial and Injector. In addition the Protector equilibrates the pressure difference which occurs when fluid

or air is added or removed from the drug vial. Liquid transfer takes place through tightly fitting elastomeric membranes to minimize exposure to potentially hazardous drug aerosols and spills that occur during the reconstitution, administration and disposal processes. Protector 14 is designed to fit smaller neck vials (vial cap diameter 14 mm) while the predicate device Protector 20 is designed to fit the standard neck drug vials (vial cap diameter 21 mm). The volume of the expansion chamber is 20 ml.

**PhaSeal, Injector Luer Lock – Drug Transfer Needle Device**

**Injector Luer Lock** is a single lumen needle that is encapsulated in a plastic chamber. One end of the **Injector Luer Lock** locks onto an external device equipped with Luer Lock fitting. Liquid transfer takes place through tightly fitting elastomeric membranes to minimize exposure to potentially hazardous drug aerosols and spills that occur during the reconstitution, administration and disposal processes. **Injector Luer Lock** is equipped with a Luer Lock fitting instead of the Luer fitting of the predicate device (Injector Luer). Also, the **Injector Luer Lock** has a wider cannula for increased flow compared to the predicate device.

**PhaSeal, Infusion Adapter – Intravascular Administration Set**

The **Infusion Adapter** serves as the connecting part between the IV bag and an external IV line. The **Infusion Adapter** has a built in Connector which makes it possible to admix drugs into the infusion solution using the sealed double membrane technique. Liquid transfer takes place through tightly fitting elastomeric membranes to minimize exposure to potentially hazardous drug aerosols and spills that occur during the reconstitution, administration and disposal processes.

**Comparison of Predicate Devices/Equivalence**

All devices are substantially equivalent to previously accepted PhaSeal devices included in 510(k) Number K972527 and K980381.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 12 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Kjel Andreasson  
Head of Quality Assurance and  
Regulatory Affairs Department  
Carmel Pharma AB  
Box 5352  
SE-402 28 Göteborg, SWEDEN

Re: K001368  
Trade Name: Protector 21, Protector 50, Protector 14,  
Injection Luer Lock, and Infusion Adapter  
Regulatory Class: II  
Product Code: LHI  
Dated: April 25, 2000  
Received: May 1, 2000

Dear Sir/Madam Andreasson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of


Page 2 - Sir/Madam Andreasson

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

  
for Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control,  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Exhibit 3 - Indications for Use Statement**

Device Name: **PhaSeal®** - a System for Closed handling of Parenteral Drugs

**PhaSeal Protector 21 - Drug Vial Transfer Adapter**

The **Protector 21** is fitted to the drug vial and is used as a docking station between the drug vial for the parenteral drug and Injector. In addition the Protector equilibrates the pressure difference which occurs when fluid or air is added or removed from the drug vial. Liquid transfer takes place through tightly fitting elastomeric membranes to minimize exposure to potentially hazardous drug aerosols and spills that can occur during the reconstitution, administration and disposal processes.

**PhaSeal Protector 50 - Drug Vial Transfer Adapter**

The **Protector 50** is fitted to the drug vial and is used as a docking station between the drug vial for the parenteral drug and Injector. In addition the Protector equilibrates the pressure difference which occurs when fluid or air is added or removed from the drug vial. Liquid transfer takes place through tightly fitting elastomeric membranes to minimize exposure to potentially hazardous drug aerosols and spills that can occur during the reconstitution, administration and disposal processes.

**PhaSeal Protector 14 - Drug Vial Transfer Adapter**


The **Protector 14** is fitted to the drug vial and is used as a docking station between the drug vial for the parenteral drug and Injector. In addition the Protector equilibrates the pressure difference which occurs when fluid or air is added or removed from the drug vial. Liquid transfer takes place through tightly fitting elastomeric membranes to minimize exposure to potentially hazardous drug aerosols and spills that can occur during the reconstitution, administration and disposal processes.

**PhaSeal Injector Luer Lock – Drug Transfer Needle Device**

The **Injector Luer Lock** is designed with an encapsulated single lumen cannula which can be assembled to an external device equipped with Luer lock fitting, such as a disposable syringe or an IV administration set of the users choice. The other end of Injector Luer Lock is sealed with a thermoplastic elastomeric membrane. The bayonet fitting allows the two elastomeric membranes to be mated together. Sealed transfer between the various components of the system can be made via the Injector Luer Lock in the preparation phase as well as the administration phase.

**PhaSeal Infusion Adapter – Intravascular Administration Set**

The **Infusion Adapter** serves as the connecting part between the IV bag and an external IV line (example IV regulators). The **Infusion Adapter** has a built-in Connector which makes it possible to admix drugs into the infusion solution using the sealed double membrane technique.

  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number 4001368